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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,450	08/19/2003	Bernhard Hermann Heinrich Breier	ERNZ-01018US1	4401

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EXAMINER	
KOSAR, ANDREW D	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 02/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/643,450	BREIER ET AL.	
	Examiner	Art Unit	
	Andrew D Kosar	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-18* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-18 are pending and require restriction.

Priority

Applicant claim for the benefit of priority as a CIP of Application 10/450,232 is acknowledged, however, as indicated in the previous Office mailing (RESPONSE TO REQUEST FOR CORRECTED FILING RECEIPT, Mailed 12/07/2004), "A claim for priority cannot be made based on an application filed after the application making the claim."

The filing date granted to the instant Application is August 19,2003.

The filing date granted to Application 10/450,232 is October 24, 2003.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 3, drawn to a method of down-regulating the density/distribution of angiotensin II receptors comprising administration of IGF-1, or IGF-1 analog, classified in class 514, subclass 21.

II. Claim 4, drawn to a method of up-regulating the density/distribution of angiotensin II receptors comprising administration of IGF-1, or IGF-1 analog, classified in class 514, subclass 21.

III. Claim 8, drawn to a method of modulating the density/distribution of angiotensin II receptors comprising administration of IGF-1, or IGF-1 analog, in a replicable vehicle, gene therapy, classified in class 514, subclass 44 or class 424, subclass 93.1.

IV. Claims 12 and 13, drawn to a method for decreasing the expression of angiotensin II receptors by administration of a compound effective to increase the IGF-1 concentration in a mammal, classified in class 514, subclass 2.

V. Claims 14 and 15, drawn to a method of reducing hypertension by administration of IGF-1 and an ACE inhibitor, classified in class 514, subclass 4.

VI. Claims 16 and 17, drawn to a method of reducing hypertension by administration of IGF-1 and an angiotensin II receptor antagonist, classified in class 514, subclass 4.

VII. Claim 18, drawn to a method of enhancing the antihypertensive and renoprotective properties of ACE inhibitors and angiotensin II antagonists by co-administration with IGF-1, or IGF-1 analogs, classified in class 514, subclass 4.

Claims 1, 2, 5-7, and 9-11 link(s) inventions I, II, and III. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s). Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable.

In re Ziegler, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to different methods with differing modes of operation, which are administering different compounds, which have different effects and different functions. Invention I and II are drawn to paradoxical effects – up-regulation and down-regulation of angiotensin II receptors. Invention III is drawn to a method of gene therapy. Invention IV does not require any compound from the other Inventions, e.g.- specifically administering IGF-1, or an analog. Inventions V and VI are drawn to reducing hypertension by combination therapy through administration of two distinct classes of compounds, ACE inhibitors or angiotensin II antagonists, which have distinct effects. Invention VII is drawn to enhancing the effects of ACE inhibitors or angiotensin II antagonists, the desired effect is not the same as any other group. The results and effects of each of the methods is distinct, one from another.

The search for each of the above inventions is not co-extensive particularly with regard to the non-patented literature search. Further, a reference which would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. For example, a search of the literature pertinent to up-regulation of angiotensin II receptor density would not necessarily lead to the discovery of any, or all, literature related to co-administration of IGF-1 with an ACE inhibitor to enhance the antihypertensive and renoprotective properties of the ACE

inhibitor. Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search for one invention would not necessarily lead to the discovery of another invention, restriction for examination purposes as indicated is proper, and to not restrict would be an undue burden on the Examiner.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

This application contains claims directed to the following patentably distinct species of the claimed invention: IGF-1, IGF-2, and des(1-3)IGF-1 in claim 2; 11 distinct ACE inhibitors in claim 15; and 5 distinct angiotensin II antagonists in claim 17.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 3-18 are generic, with respect to IGF compounds; claims 14 and 18 are generic, with respect to ACE inhibitors; and claims 16 and 18 are generic, with respect to angiotensin II antagonists.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the

limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Miscellaneous Communications

Applicant's communication of October 13, 2004 is acknowledged, requesting that the Office not enter the previous Request to Correct Filling Receipt (September 30, 2004). Applicant stated the Application number was incorrect on the paper, and not part of this case. Appropriate actions have been taken.

NO CLAIMS ARE ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew D. Kosar whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 8am-430pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571)272-0974. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Andrew D. Kosar, Ph.D.
Patent Examiner
Art Unit 1654

CHRISTOPHER R. TATE
PRIMARY EXAMINER